

PTO/SB/21 (09-04)


Approved for use through 07/31/2006. OMB 0651-0031

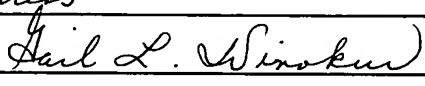
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|  |                      |                        |           |
|--|----------------------|------------------------|-----------|
| <b>TRANSMITTAL<br/>FORM</b><br><br><small>(to be used for all correspondence after initial filing)</small> | Application Number   | 10k/517,214            |           |
|  | Filing Date          | 11/23/2004             |           |
|  | First Named Inventor | T. MAEKAWA             |           |
|  | Art Unit             | tba                    |           |
|  | Examiner Name        | tba                    |           |
| Total Number of Pages in This Submission   | 16                   | Attorney Docket Number | 3065 US0P |

| ENCLOSURES (Check all that apply)   |  |  |
|---|--|--|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input checked="" type="checkbox"/> Reply to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify<br>below):<br>Return Postcard;<br>Certificate of Express Mailing;<br>Submission of Written Sequence Listing;<br>IBM PC/AT format disk;<br>Copy of Notification to Comply |
| Remarks<br>The Commissioner is hereby authorized to charge any additional fees which may be required,<br>or credit any overpayment to Deposit Account 500799.   |  |  |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT |   |                 |
|--|---|-----------------|
| Firm Name                                  |   |                 |
| Signature                                  |  |                 |
| Printed name                               | Mark Chao, Ph.D., JD  |                 |
| Date                                       | 12/21/05  | Reg. No. 37,293 |

| CERTIFICATE OF TRANSMISSION/MAILING   |   |                 |
|---|---|-----------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with<br>sufficient postage as <del>first class</del> <i>Express</i> mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on<br>the date shown below: |   |                 |
| Signature   |  |                 |
| Typed or printed name   | Gail L. Winokur   | Date 12/21/2005 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

*Express Mail No. EV 6840 83839 US*

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                           |   |            |     |
|---------------------------|---|------------|-----|
| Application No.:          | 10/517,214  | Art Unit:  | tba |
| Filed:                    | 11/23/2004  | Examiner:  | tba |
| 1 <sup>st</sup> Inventor: | T. MAEKAWA  | Allowed:   |     |
| For:                      | 1,2-Azole Derivatives with Hypoglycemic and<br>Hypolipidemic Activity | Batch:     |     |
| Atty. Dkt. No.            | 3065 USOP   | Paper No.: |     |

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 684083839 US

DATE IN: December 21, 2005

**Itemized Papers/Items:**

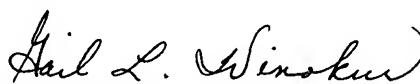
1. This Certificate of Express Mailing and Return Postcard (2 pages)
2. Transmittal Form (1 page X 2)
3. Response to Notice to Comply with Sequence Listing Requirements (1 page), Submission of Written Sequence Listing (3 pages), IBM PC/AT format disk containing the CRF of the Sequence Listing,
4. Copy of Notification to Comply (8 pages).

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP SEQUENCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on this date, December 21, 2005

Dated: 12/21/05

  
Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

395



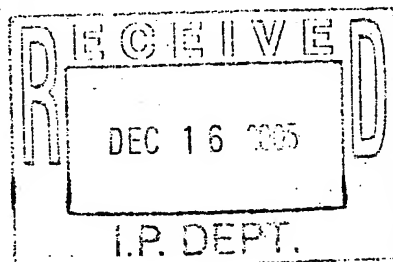
## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
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P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/517,214                  | Tsuyoshi Maekawa      | 3065 USOP        |

23115  
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

|                               |               |
|-------------------------------|---------------|
| INTERNATIONAL APPLICATION NO. |               |
| PCT/JP03/06389                |               |
| I.A. FILING DATE              | PRIORITY DATE |
| 05/22/2003                    | 05/24/2002    |



CONFIRMATION NO. 7396

371 FORMALITIES LETTER



\*OC000000017640406\*

Date Mailed: 12/13/2005

### NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

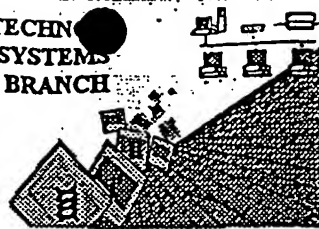
KAREN M WILLIAMS

Telephone: (703) 308-9140 EXT 213

## PART 1 - ATTORNEY/APPLICANT COPY

|                             |                               |                  |
|-----------------------------|-------------------------------|------------------|
| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
| 10/517,214                  | PCT/JP03/06389                | 3065 USOP        |

FORM PCT/DO/EO/922 (371 Formalities Notice)



## RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:

10/517,214

Source:

PCF

Date Processed by STIC:

12-22-04

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 06/05/04):  
U.S. Patent and Trademark Office, 220 20<sup>th</sup> Street S., Customer Window, Mail Stop Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, VA 22202

Revised 05/17/04



PCT

## RAW SEQUENCE LISTING

DATE: 12/22/2004

PATENT APPLICATION: US/10/517,214

TIME: 09:16:36

Input Set : A:\3065 USOP seq.txt

Output Set: N:\CRF4\12222004\J517214.raw

2 <110> APPLICANT: MAEKAWA, Tsuyoshi  
 3 HARA, Ryoma  
 4 ODAKA, Hiroyuki  
 5 MIZUFUNE, Hideya  
 6 FUKATSU, Kohji  
 8 <120> TITLE OF INVENTION: 1,2-Azole Derivatives with Hypoglycemic and Hypolipidemic Activity  
 10 <130> FILE REFERENCE: 3065 USOP  
 C--> 12 <140> CURRENT APPLICATION NUMBER: US/10/517,214  
 C--> 12 <141> CURRENT FILING DATE: 2004-11-23  
 12 <150> PRIOR APPLICATION NUMBER: PCT/JP03/06389  
 13 <151> PRIOR FILING DATE: 2003-05-22  
 15 <150> PRIOR APPLICATION NUMBER: JP 2002-151405  
 16 <151> PRIOR FILING DATE: 2002-05-24  
 18 <150> PRIOR APPLICATION NUMBER: JP 2002-287161  
 19 <151> PRIOR FILING DATE: 2002-09-30  
 21 <150> PRIOR APPLICATION NUMBER: JP 2003-016748  
 22 <151> PRIOR FILING DATE: 2003-01-24  
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 53 <400> SEQUENCE: 3  
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 56 <210> SEQ ID NO: 4

Does Not Comply  
 Connected Discontinuity

(pg. 2)

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/517,214

DATE: 12/22/2004

TIME: 09:16:36

Input Set : A:\3065 USOP seq.txt

Output Set: N:\CRF4\12222004\J517214.raw

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118 <211> LENGTH: 33

pls explain source  
of genetic material.  
See item # 11  
on error summary  
sheet.

## RAW SEQUENCE LISTING

DATE: 12/22/2004

PATENT APPLICATION: US/10/517,214

TIME: 09:16:36

Input Set : A:\3065 USOP seq.txt

Output Set: N:\CRF4\12222004\J517214.raw

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W--> 146 ??  
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W--> 150 ??  
W--> 152 ??

*PLS  
delete*



## VERIFICATION SUMMARY

PATENT APPLICATION: US/10/517,214

DATE: 12/22/2004

TIME: 09:16:37

Input Set : A:\3065 USOP seq.txt

Output Set: N:\CRF4\12222004\J517214.raw

L:12 M:270 C: Current Application Number differs, Replaced Current Application No  
L:12 M:271 C: Current Filing Date differs, Replaced Current Filing Date  
L:30 M:283 W: Missing Blank Line separator, <220> field identifier  
L:40 M:283 W: Missing Blank Line separator, <220> field identifier  
L:50 M:283 W: Missing Blank Line separator, <220> field identifier  
L:60 M:283 W: Missing Blank Line separator, <220> field identifier  
L:70 M:283 W: Missing Blank Line separator, <220> field identifier  
L:84 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:6,Line#:82  
L:91 M:283 W: Missing Blank Line separator, <220> field identifier  
L:101 M:283 W: Missing Blank Line separator, <220> field identifier  
L:111 M:283 W: Missing Blank Line separator, <220> field identifier  
L:121 M:283 W: Missing Blank Line separator, <220> field identifier  
L:131 M:283 W: Missing Blank Line separator, <220> field identifier  
L:141 M:283 W: Missing Blank Line separator, <220> field identifier  
L:146 M:334 W: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:1  
L:148 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12  
L:148 M:334 W: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:1  
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L:152 M:334 W: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:1

## STATISTICS SUMMARY

PATENT APPLICATION: US/10/517,214

DATE: 12/22/2004

TIME: 09:16:37

Input Set : A:\3065 USOP seq.txt

Output Set: N:\CRF4\12222004\J517214.raw

Application Serial Number: US/10/517,214

Alpha or Numeric or Xml: Numeric

Application Class:

Application File Date: 11-23-2004

Art Unit: PCT

Software Application:

Total Number of Sequences: 12

Total Nucleotides: 394

Total Amino Acids: 0

Number of Errors: 0

Number of Warnings: 19

Number of Corrections: 2

## MESSAGE SUMMARY

258 W: 1 (Mandatory Feature missing)

270 C: 1 (Current Application Number differs)

271 C: 1 (Current Filing Date differs)

283 W: 11 (Missing Blank Line separator)

334 W: 4 ((2) Invalid Amino Acid in Coding Region)

336 W: 3 (Invalid Amino Acid Number in Coding Region)